Update on EPA's Pesticide Program Activities

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Discussion Topics

- Office of Pesticide Programs 2020 Goals & Priorities
- Assessing Risk to Pollinators
- Pesticide Mixtures
- Risk Management Considerations
- Pollinator Protection Plans
- Chemical Decisions

OPP Goals and Priorities

Goals of Pesticide Decision-Making in EPA's Office of Pesticide Programs

- Protect human health and the environment from pesticide risks
- Effectively assess, manage, and mitigate risks based on the best available science
- Promote safer pest control
- Operate with transparency and consultation with stakeholders throughout the process

FY 2020 OPP Priorities: Protecting Human Health and the Environment

- Meeting PRIA statutory deadlines for registration actions
- Progressing the registration review program
- Advancing critical science and policy issues
- Working collaboratively with state partners and other stakeholders to implement program
- Implementing EPA Lean Management System (ELMS) across OPP
- Gaining efficiencies by utilizing LEAN Six Sigma principles for identified selective processes

Assessing the Effect of Pesticides on Bees and other Pollinators

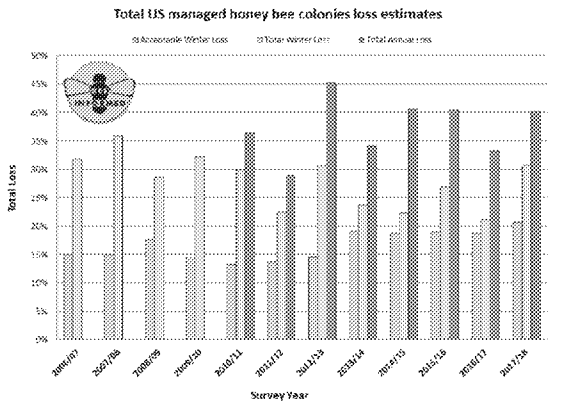
Status of Managed and Wild Bee Losses in the U.S.

Honey bees

- Avg. overwintering colony loss since 2008: 27.9%
- Overwintering loss (2017 – 2018): 30.7%
- Total annual loss: 40.1%

Wild bees (~3,500 spp. in North America)

- Populations of some species of wild bees are in decline
- Since 2017, several species of bees added to the Endangered Species List:
  - Yellow-faced bees
  - Rusty patched bumble bee



Source: https://beeinformed.org/results/honey-bee-colony-losses-2017-2018-preliminary-results/

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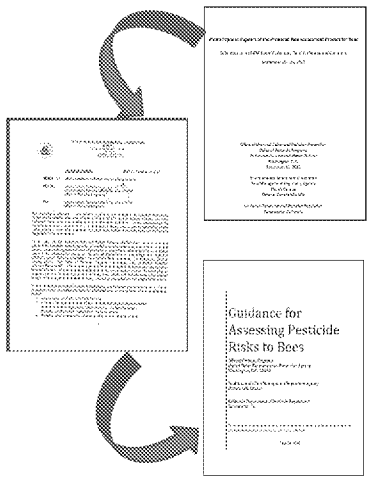
Assess the Effect of Pesticides on Bees and other Pollinators

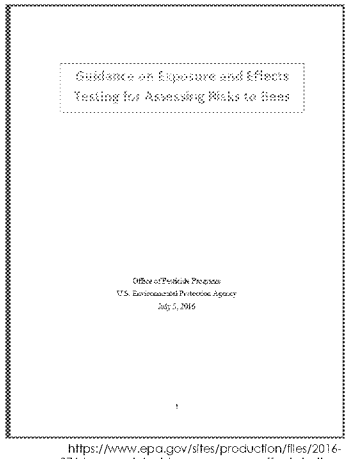
- 2011: Interim Guidance on Honey Bee Data Requirements
- 2012: Pollinator Risk Assessment Framework White Paper
- 2014: Final EPA Guidance on Risk Assessments for Pollinating Bees



https://www.epa.gov/sites/production/files/2014-06/documents/pollinator_risk_assessment_guidance_06_19_14.pdf

Assess the Effect of Pesticides on Bees and other Pollinators

- 2016 Guidance on Exposure and Effects Testing for Assessing Risks to Bees
  - Tier 1
    - Adult acute contact/oral;
    - Adult chronic 10-day;
    - Larval acute;
    - Larval chronic 22-day
  - Tier II
    - Semi-field (tunnel; feeding) Colony;
    - Residues in pollen/nectar.
  - Tier III
    - Full-field Colony


Guidance on Exposure and Effects Testing for Assessing Risks to Bees

Office of Pesticide Programs
U.S. Environmental Protection Agency
July 7, 2016

https://www.epa.gov/sites/production/files/2016-07/documents/guidance-exposure-effects-testing-assessing-risks-bees.pdf

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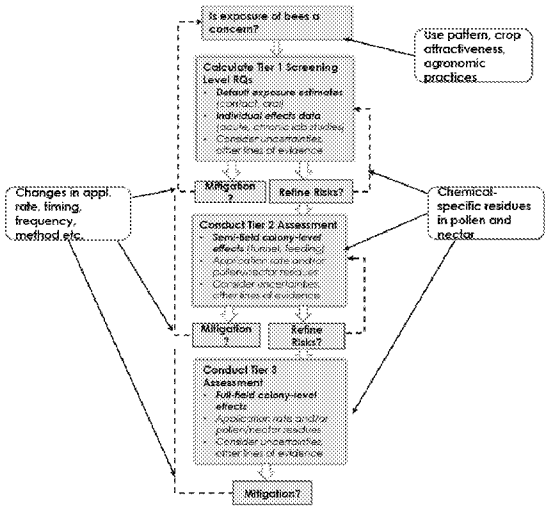
Tiered Risk Assessment Process

- Screening-level risk estimates based on Tier 1 acute and chronic laboratory studies with adult and larval bees
- Higher-tier studies with honey bee colonies may be required pending the outcome of the Tier 1 analysis and risk manager need for additional refinement



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Pesticide Mixtures

Pesticide Mixtures

- EPA participated in a collaborative pilot study with the California Department of Pesticide Regulation to identify common pesticide mixtures used on almonds and based on California Pesticide Use Reporting (PUR)
- Data indicate that a wide array of products are tank mixed during the almond bloom period (Feb – Apr).
- There are multiple combinations even for a limited number of actives that are tank mixed.
- Tank mixes are applied to a relatively low percentage of acreage (*i.e.*, relatively low percent crop treated).
- Tank mixes of insecticides with fungicides in almonds occurred most frequently well before or after peak bloom.

Pesticide Mixtures

- While use data may be available for California, similar data are not available for other states and are likely commodity/ pest-pressure dependent.
- In the absence of similar use information for other states and the number/variety of tank mix combinations, it's not feasible to require toxicity testing on such combinations at this time to support risk assessments at a National level.
- Individual pesticides which may be used as a component of a mixture have already been mitigated to meet the FIFRA standard of no unreasonable risk to the environment.

Risk Management Considerations

EPA Legal Standards

Regulatory Framework for U.S. pesticide regulation

- Federal Insecticide, Fungicide & Rodenticide Act (FIFRA)
  - *Risk-benefit standard* - considers human and ecological risk and benefits of pesticides
- Federal Food, Drug & Cosmetic Act (FFDCA)
  - *Risk-only standard* - governs allowable pesticide residues in/on food
- Food Quality Protection Act (FQPA) amended FFDCA and FIFRA
  - Stricter standards for pesticides on food; risks to infants/children

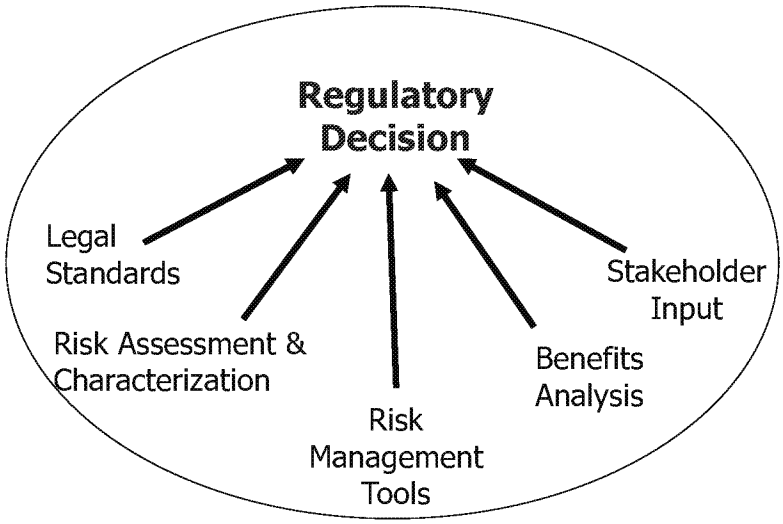
EPA Risk Assessment & Characterization

Risk = *f*(Hazard, Exposure)

- *Risk assessment* is the process EPA uses to evaluate the potential for health and ecological effects of a pesticide's use.
- *Risk characterization* is the quantitative and qualitative evaluation of factors that help decision-makers understand the likelihood of occurrence and the nature of the effects of pesticide use.
  - Describes level of confidence and uncertainty

EPA

Risk Management



EPA Risk Management Definition

The process by which risk assessment and risk characterization results are integrated with other information (i.e. economic, legal) to make decisions about the need for, method of, and extent of risk reduction.

EPA Benefits and Impact Assessments

- Benefits refer to the value of pesticides to the user compared to next best alternative
  - Develop information about pesticide use patterns
  - Evaluate alternative pesticides or pest control practices
- Impact assessments seek to address the estimated impact of risk management actions
  - Changes in use pattern, application method, equipment, etc.
- USDA is an important source of information
  - Provide insights into grower needs and practices

Stakeholder Input

- User Groups
- Registrants
- Worker Advocacy Groups
- Environmental Advocacy Groups
- Beekeepers
- States
- Other Federal Agencies
- General Public

Mitigating Risks: Pollinator Protection Plans

Acute Risk Mitigation Policy

EPA's Policy to Mitigate the Acute Risk to Bees from Pesticide Products[1] - issued January 12, 2017

- Two Mitigation Strategies:
  1. Seeks label Restrictions for Contract Pollination Services
  2. State and Tribal Managed Pollinator Protection Plans (MP3s) for Bee Colonies Not under Contract Pollination Services

[1] https://www.epa.gov/pollinator-protection/policy-mitigating-acute-risk-bees-pesticide-products

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Managed Pollinator Protection Plans (MP3)

- EPA continues to encourage development of MP3/P3s for States and Tribes and is available to provide assistance
- States have engaged stakeholders (growers, applicators and beekeepers)
  - Most states have a plan in place;
  - The majority of plans are voluntary;
  - For more information - https://aapco.org/2015/07/20/current-topics/
- Tribal Nations working with the Tribal Pesticide Program Council (TPPC) to develop P3s with a focus on native pollinators
  - Several tribes have or will be developing plans
  - For more information - http://tppcwebsite.org/pollinators/

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Evaluating the Effectiveness of MP3s

- EPA needs a means to collectively evaluate the individualized, state-specific approaches to pollinator protection
- The Pesticide Program Dialogue Committee (PPDC) is a broadly representative federal advisory committee that meets with EPA to discuss pesticide regulatory, policy and program implementation issues

  https://www.epa.gov/pesticide-advisory-committees-and-regulatory-partners/pesticide-program-dialogue-committee-ppdc
- Workgroup formed in 2016 to:

  1) develop recommendations for how to evaluate the effectiveness of state and tribal pollinator protection plans at the national level, and,

  2) formulate a strategy to communicate that effectiveness to the public

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Evaluating the Effectiveness of MP3s

- PPDC recommended development of a survey instrument;
- State lead agencies assisting in development/deployment of the survey
- Survey questions include measures of communication, development of best management practices (BMPs)/standard operating procedures (SOPs); education/outreach; stakeholder engagement; and, measures of behavior change/progress.
- Survey results from states provided to EPA in late 2019
  - EPA reviewing results of the survey
  - Biennial
  - Initial survey year serves as a baseline
- Survey results provide EPA a line of evidence in determining the efficacy of MP3 relative to reducing exposure of bees to pesticides.

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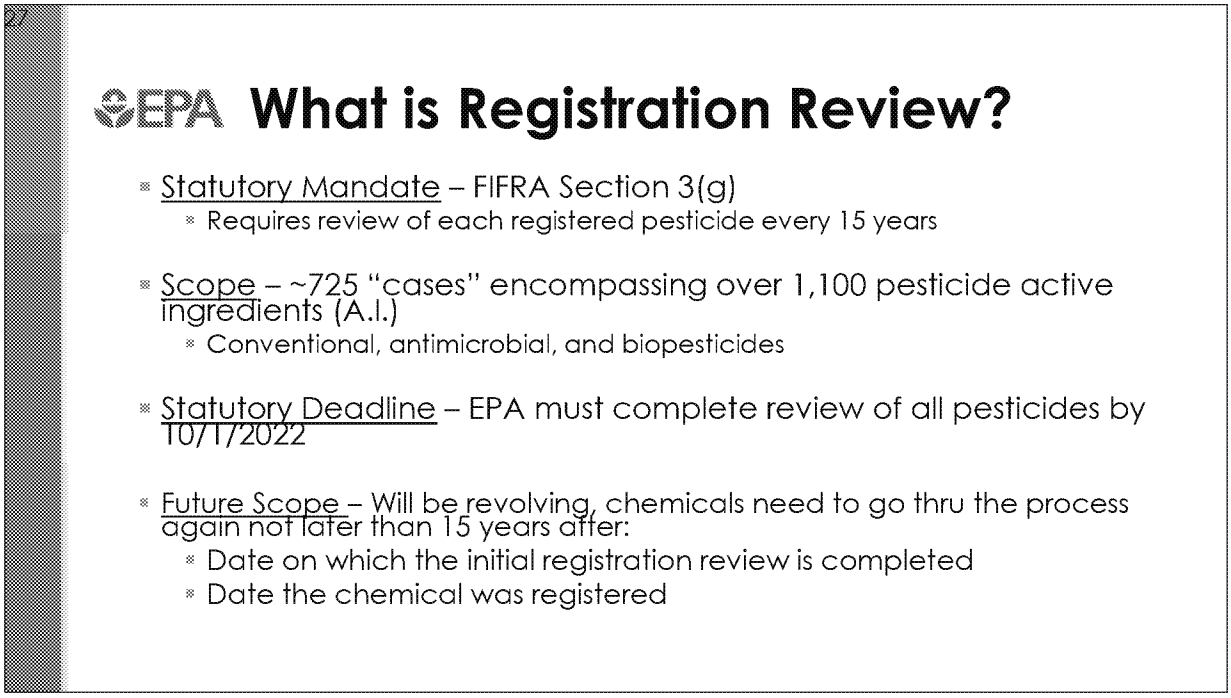
Chemical Decisions



First round of registration review started in Oct. 2007

EPA Neonicotinoid Registration Review

- **2010-2011:** Imidacloprid, thiamethoxam, clothianidin, and dinotefuran
- **2014:** Published a benefits assessment on the treatment of soybean seeds with neonicotinoids
- **2016-2017:** Published the preliminary pollinator assessments
- **2017:** Published draft human health risk assessment
- **2017:** Published additional benefits assessments on cotton and citrus, along with a revised seed treatment assessment
- **2017-2018:** Received new pollinator toxicity and exposure data
- **Regulatory Updates**
  - EPA's preliminary pollinator assessments noted the potential for on-field risk from some uses. However, risk was considered to be low for other uses such as seed treatments.
  - EPA's draft ecological risk assessments noted potential risk to aquatic invertebrates from drift and run-off, as well as to birds and mammals from potential exposure to treated seed.
  - In early 2020, EPA anticipates publishing the Proposed Interim Decisions for imidacloprid, thiamethoxam, clothianidin, and dinotefuran.

Sulfoxaflor

- July 12, 2019 EPA issued approval for sulfoxaflor for use on variety of crops
- Poses no significant risk to human health and lower risk to non-target wildlife, including pollinators, than registered alternatives
- Provides benefits to growers as an effective tool against difficult pests, such as sugarcane aphids and tarnished plant bugs (Lygus)
- Supported by strong science that shows minimal risks for pollinators; included review of one of the Agency's largest datasets on effects of pesticides on bees

EPA